510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

Contact: James A. Lee, Ph.D.
Regulatory Affairs Specialist

Device Identification:

Common Name:
Flexible Fiberscope

Trade Name: (optional)
Karl Storz Fiberscope

Indication: The KSEA Fiberscope is indicated for use to provide visualization of the pericardium and cardiac chambers during endoscopic heart surgery procedures.

Device Description: The KSEA Fiberscope is a manually operated surgical device. The KSEA Fiberscope is flexible fiberoptic telescope which utilizes fiber-optic technology.

Substantial Equivalence: The KSEA Fiberscope is substantially equivalent to the predicate devices since the basic features, design, body contact material and general intended uses are the same. The KSEA Fiberscope does not incorporate any significant change that could affect safety or effectiveness. The minor differences between the KSEA Fiberscope and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function or intended use of the devices.

Signed: _____

James A. Lee, Ph.D.
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2002

James A. Lee, Ph.D.
Regulatory Affairs Specialist
Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe 5th Floor
Culver City, CA 90230

Re: K011793
Trade Name: KSEA Fiberscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II (two)
Product Code: 74 LYK
Dated: January 31, 2002
Received: February 1, 2002

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

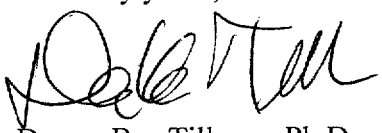
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

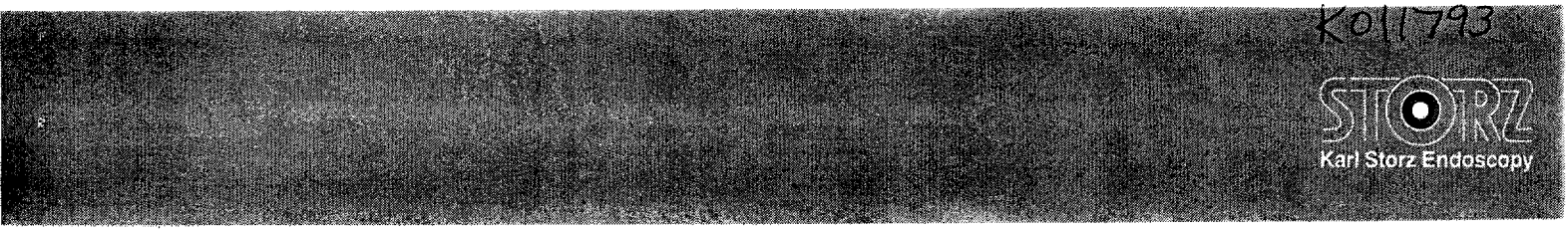
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Number (if known): K011793

Device Name: KSEA Fiberscope

Indications for Use: The KSEA Fiberscope is indicated for use to provide visualization of the pericardium and cardiac chambers during endoscopic heart surgery procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011793